



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0387; FRL-10030-01-OCSP]

Cyclaniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyclaniliprole in or on multiple crops that are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0387, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency,

1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How Can I File an Objection or Hearing Request?

Under FFDCFA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0387 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0387, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of October 21, 2021 (86 FR 58239) (FRL-8792-04-OCSP) and April 28, 2022 (87 FR 25178) (FRL-9410-12-OCSP), EPA issued documents pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8904) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to establish tolerances for residues of the insecticide cyclaniliprole, 3-bromo-*N*-[2-bromo-4-chloro-6-[[[(1-cyclopropylethyl)amino]carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, including its metabolites and degradates,

in or on the raw agricultural commodities: Artichoke, globe at 1.5 parts per million (ppm); Pepper/eggplant subgroup 8-10B at 1.5 ppm; Sunflower subgroup 20B at 0.4 ppm; Tomato subgroup 8-10A at 0.6 ppm; Hog, meat at 0.01 ppm; Hog, fat at 0.015 ppm; Hog, meat byproducts at 0.015 ppm; Egg at 0.01 ppm; Poultry, meat at 0.01 ppm; Poultry, fat at 0.015 ppm; and Poultry, meat byproducts at 0.015 ppm. Upon the establishment of the tolerances specified above, IR-4 requested to remove the established tolerance for Vegetable, fruiting, group 8-10 at 0.20 ppm. The documents referenced a summary of the petition, which is available in the docket, <https://www.regulations.gov>. There were no substantive comments received in response to the notices of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the commodities for which tolerances are being set.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate

exposure for cyclaniliprole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyclaniliprole follows.

No single or repeated dose study performed by any route of exposure produced an adverse effect following cyclaniliprole exposure at dose levels below, at, or above the limit dose (1,000 milligrams/kilogram/day (mg/kg/day)). Although the oral toxicity studies in dogs were conducted at approximately a third of the limit dose, no adverse effects were seen. While adaptive liver effects were seen in these studies, it is unlikely that cyclaniliprole would produce adverse liver effects if tested at higher doses in dogs as a structurally related chemical, chlorantraniliprole, was tested up to the limit dose in dogs and did not demonstrate adverse liver effects. There is no evidence that cyclaniliprole produces increased susceptibility with prenatal or postnatal exposures. Cyclaniliprole is considered not likely to be carcinogenic based on no increase in treatment-related tumor incidence in carcinogenicity studies in rats and mice and no genotoxicity.

Specific information on the studies received for cyclaniliprole as well as the no-observed-adverse-effect-level (NOAEL) from the toxicity studies can be found at <https://www.regulations.gov> in document, “Cyclaniliprole: Human Health Risk Assessment for the Proposed New Uses on Globe Artichoke and Sunflower Subgroup 20B and for new Greenhouse Uses (with Amended Tolerances) on Tomato Subgroup 8-10A and Pepper/Eggplant Subgroup 8-10B”, in docket ID number EPA-HQ-OPP-2021-0387.

Based on the review of the available cyclaniliprole toxicological studies, no toxicity endpoints or points of departure were selected for risk assessment. Based on the toxicological profile of cyclaniliprole, EPA has concluded that the FFDC requirements to retain an additional safety factor for protection of infants and children and to consider cumulative effects do not apply. Section 408(b)(2)(C) requires an additional tenfold margin of safety in the case of threshold risks, which cyclaniliprole does not present. Section 408(b)(2)(D)(v) requires consideration of information concerning cumulative effects of substances that have a common

mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyclaniliprole and any other substances, and cyclaniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that cyclaniliprole has a common mechanism of toxicity with other substances.

Cyclaniliprole has been grouped with the pyridyl pyrazoles. As part of the ongoing process to review registered pesticides, the Agency intends to apply this framework to determine if the available toxicological data for cyclaniliprole suggests a candidate common mechanism group (CMG) may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

There is a potential for exposure to cyclaniliprole residues via food and drinking water based on existing uses and the proposed uses for cyclaniliprole application directly to growing crops. These applications can also result in cyclaniliprole reaching surface and ground water, both of which can serve as sources of drinking water. There are no existing or proposed uses in residential settings and therefore no anticipated residential exposures, although exposures resulting from spray drift from agricultural applications onto residential areas may occur. However, no quantitative risk assessment was conducted because no toxicity endpoints or points of departure were selected for risk assessment.

Determination of safety. Based on the available data indicating a lack of adverse effects from exposure to cyclaniliprole, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to cyclaniliprole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography with tandem mass spectrometry (LC-MS/MS)) is available to enforce the tolerance expression for plants and livestock commodities. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4).

The Codex has established MRLs for cyclaniliprole. The tolerance definitions are harmonized between the U.S. and Codex for plant and livestock commodities. There are Codex MRLs established on tomato subgroup 8-10A at 0.08 ppm for most commodities and at 0.1 ppm for tomato and on pepper/eggplant subgroup 8-10B at 0.15 ppm. For peppers (bell/non-bell) and tomatoes, the Agency is not harmonizing with the Codex MRLs because the Codex MRLs are much lower than the U.S. tolerances (0.15 vs 1.5 ppm for pepper subgroup and 0.1 vs 0.7 ppm for tomato subgroup). Harmonization could potentially result in tolerance exceedances in the U.S. and is therefore not possible.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the tolerance value for tomato subgroup 8-10A from 0.6 ppm to 0.7 ppm because EPA used different residue data to calculate the tolerance. The proposed preharvest interval (PHI) for tomato is 1 day and the petitioner used residue data from a 1-day PHI. The decline trial indicated that residues increased at higher PHIs, so EPA included the highest cyclaniliprole residue at a PHI of 7 days in the tolerance calculation to be conservative.

EPA has determined that tolerances for Hog, meat; Hog, fat; Hog, meat byproducts; Egg; Poultry, meat; Poultry, fat; and Poultry, meat byproducts are not necessary because the calculated dietary burdens for swine and poultry are very low such that there is no reasonable expectation of finite residues in these commodities as a result of eating treated feedstuff (40 CFR 180.6(a)(3)).

V. Conclusion

Although the lack of toxicity supports a safety finding for an exemption from the requirement of tolerance for all crops, EPA is establishing tolerances for residues resulting from direct applications to certain commodities because the petitioner requested them for international trade purposes. Therefore, tolerances are established for residues of cyclaniliprole in or on Artichoke, globe at 1.5 ppm; Pepper/eggplant subgroup 8-10B at 1.5 ppm; Sunflower subgroup 20B at 0.4 ppm; and Tomato subgroup 10A at 0.7 ppm. Additionally, the tolerance for Vegetable, fruiting, group 8-10 is removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCFA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: November 15, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.694, amend the table in paragraph (a) by:

a. Adding a heading;

b. Adding in alphabetical order the entries “Artichoke, globe”, “Pepper/eggplant subgroup 8-10B”, “Sunflower subgroup 20B”, and “Tomato subgroup 8-10A”; and

c. Removing the entry for “Vegetable, fruiting, group 8-10”.

The additions read as follows:

§ 180.694 Cyclaniliprole; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	* *
Artichoke, globe	1.5
* * * * *	* *
Pepper/eggplant subgroup 8-10B	1.5
* * * * *	* *
Sunflower subgroup 20B	0.4
* * * * *	* *
Tomato subgroup 8-10A	0.7
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